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14. ABSTRACT

This randomized, single blind study is evaluating the efficacy of virtual reality exposure therapy (VRET) by comparing it to prolonged exposure therapy (PE) and a waitlist (WL) group in the treatment of post-traumatic stress disorder (PTSD) in active duty (AD) Soldiers with combat-related trauma. During the first year, the study team developed the infrastructure to implement the trial including personnel hiring and training, process development to identify, screen, and enroll participants, completion of study-related VR Iraq scenarios, and research protocol development. During the second year, recruitment and enrollment of soldiers for study participation began, and by the end of year two 145 referrals for treatment had been received, 84 subjects consented to study participation and 45 met all of the inclusion and none of the exclusion criteria and were randomized to treatment. The current reporting period that covers year 3 included the ongoing recruitment, assessment and treatment of soldiers in the study, the implementation of new physiological recording equipment, assessment of additional advertisement campaigns, and ongoing study related activities. During year 3, an additional 100 referrals for treatment have been received, 72 subjects consented to study participation and 39 of those met all of the inclusion and none of the exclusion criteria and were randomized.

15. SUBJECT TERMS
PTSD, virtual reality exposure therapy (VRET), prolonged exposure therapy (PE)

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INTRODUCTION.

This randomized, single blind study is evaluating the efficacy of virtual reality exposure therapy (VRET) by comparing it to prolonged exposure therapy (PE) and a waitlist (WL) group in the treatment of post-traumatic stress disorder (PTSD) in active duty (AD) Soldiers with combat-related trauma. The study will test the general hypotheses that 10 sessions of VRET will successfully treat PTSD, therapeutically affect levels of physiological arousal, and significantly reduce perceptions of stigma toward seeking behavioral health services. Soldiers returning from deployments to Iraq who are diagnosed with combat-related PTSD following administration of the Clinician-Administered PTSD Scale (CAPS) will be randomized to one of three groups: 1) PE; 2) VRET; or 3) WL. Soldiers will undergo clinical assessments at baseline and after 5 and 10 treatment sessions. Outcome measures will also be collected at 12 and 26 weeks post-treatment. Physiological arousal, patient satisfaction with treatment, and stigma toward seeking behavioral health services will also be explored.

BODY.

During this reporting period the study team has continued recruitment, enrollment and follow-up of study participants throughout the year. Comprehensive advertising campaigns, including clinic briefings, flyers, posters and websites have continued to draw potential participants. The consultant team provides ongoing treatment fidelity evaluations and the research team is conducting continuous inter-rater reliability assessments. With the resignation of the research assistant, the study team recruited, hired and trained a new research assistant.

Initial recruitment for this study began in May 2009. During this reporting period 100 referrals for treatment were received, 72 subjects consented to study participation and 39 of those met all of the inclusion and none of the exclusion criteria and were randomized to treatment. Total study numbers to date include 245 referrals, 156 subjects consented to study participation and 84 meeting all of the inclusion and none of the exclusion criteria and randomized to treatment. Of the 28 subjects randomized to the 'waitlist' condition, 24 subjects have completed study participation through the post-assessment visit, and 4 dropped from study participation, either by withdrawing consent or becoming lost to follow-up. Of the 56 subjects randomized to either active treatment group, 2 are currently "in-treatment" phase (sessions 1-10), 5 are waiting for 12 or 26 week follow-up assessments. 13 subjects have completed study participation through 26 week follow-up. 36 subjects have dropped from study participation prior to completing the 26 week follow-up, either by withdrawing consent or becoming lost to follow-up. Of these 36 drop outs, 7 completed the active treatment phase and post-treatment assessment.

Ongoing recording and review of sessions has been implemented in order to ensure treatment fidelity of 15% of treatment sessions.

<u>Modification</u>

Due to poor Bluetooth reception in the facility, the Nexus-10 equipment was not transmitting quality physiological data, with high amounts of artifact and null values present. The study team researched the benefits of using a hard-wired system using Biopac data collection

tools, and found the physiological results to be of better quality. An amendment removing the use of the Nexus-10 equipment and the addition of the Biopac system for collection of bio-physiological feedback was approved by the IRB in October of 2010.

Responses to AHRPO audit findings were submitted and accepted by the IRB.

Amendments to replace staff in the research assistant position and to add additional sub-investigators have been submitted during this reporting period. Additionally, amendments proposing advertisement materials updated to reflect the change of staff have been submitted for review to the IRB. Approval of the updated ad campaign is anticipated shortly.

Challenges

Challenges identified during this reporting period include subject recruitment and retention. Despite continuing PI and sub-I clinic updates around the installation, recruitment has remained slower than desired. New web resources such as websites linking subjects directly to recruitment information have been developed and are in the process of IRB approval.

With this reporting period covering the second year of enrollment and follow-up of participants into the study, a challenge regarding subject retention has become apparent. The study team has consulted with subject matter experts on this topic, and has identified a possible protocol amendment that would include adding an additional questionnaire to measure subject initial intent to complete the study, as well as intent to return to the next treatment session. Additional grant funding was awarded to add an additional recruitment site.

KEY RESEARCH ACCOMPLISHMENTS.

Administrative and logistical matters.

a). Personnel.

1) The replacement research assistant has been trained and is completing all study related tasks as assigned.

b) Materials, supplies and consumables.

1) Supplies and materials for study requirements continue to be coordinated in support of human subject enrollment.

2) Biopac data collection machines were obtained and are currently in-use to measure physiological feedback

c) Institutional Review Board.

1) Continuing reviews conducted by the IRB were approved December 2010 and May 2011. Ongoing amendments and modifications are submitted and addressed by IRB.

REPORTABLE OUTCOMES.

None

CONCLUSION.

None

REFERENCES.

None

APPENDICIES.
None